ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2013–0349; FRL – 10024-52-OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Pharmaceuticals Production (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), NESHAP for Pharmaceuticals Production, to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through July 31, 2021. Public comments were previously requested, via the *Federal Register*, on May 12, 2020 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An Agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].**

ADDRESSES: Submit your comments to EPA, referencing Docket ID Number EPA–HQ–OECA–2013–0349, online using www.regulations.gov (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave., NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain.

Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (202) 564-2970; fax number: (202) 564-0050**;** email address: yellin.patrick@epa.gov.

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov, or in person, at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's public docket, visit: http://www.epa.gov/dockets.

Abstract: The NESHAP for Pharmaceuticals Production were proposed on April 2, 1997, and promulgated on September 21, 1998, and amended on both April 21, 2011 and February 27, 2014. In general, all NESHAP standards require initial notifications, performance tests, and periodic reports. Owners or operators are also required to maintain records of the occurrence and duration of any malfunctions in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance and, in general, are required of all sources subject to NESHAP. This information is used by the Agency to identify sources subject to these standards to ensure that the maximum achievable control technologies are being applied. Semiannual summary reports are also required.

Form Numbers: None.

Respondents/affected entities: Pharmaceutical manufacturing operations.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart GGG).

Estimated number of respondents: 27 (total).

Frequency of response: Initially, occasionally, quarterly and semiannually.

Total estimated burden: 44,300 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $5,300,000 (per year), which includes $112,000 in annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: There is no change in burden from the most-recently approved ICR as currently identified in the OMB Inventory of Approved Burdens. This is due to two considerations: 1) the regulations have not changed over the past three years and are not anticipated to change over the next three years; and 2) the growth rate for this industry is very low or non-existent, so there is no significant change in the overall burden. Since there are no changes in the regulatory requirements and there is no significant industry growth, there are also no changes in the capital/startup or operation and maintenance (O&M) costs.

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Regulatory Support Division.

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